K071484

510(k) SUMMARY

The Summary of Safety and Effectiveness on the GluStitch, Inc. Family of PeriAcryl® reflects data available and represented at the time the submission was prepared, but caution should be exercised in interpreting the data. The results of future studies and or tests may require alterations of the conclusions or recommendations set forth.

Applicant	Don Blacklock GluStitch, Inc. 7188 Progress Way, #307 Delta, British Columbia Canada V4G 1M6
Telephone	800-667-2130
Facsimile	877-450-4000
Date	August 1, 2007
Name	Family of PeriAcryl®
Classification	Dental Cement, 21 CFR 872.3275
Predicate:	• K050658 Hager WorldWide, Inc., Hager Reso Pac Periodontal Dressing, market clearance date May 27, 2005; • K974097 Blacklock Medical Products, Inc., Periacryl, market clearance date April 9, 1998; and • K030574 GluStitch, Inc., GluSeal, market clearance date August 21, 2003.
Description	The Family of PeriAcryl® is a formulated compound of the cyanoacrylate series. It is available in 90/10 butyl/octyl, 80/20, butyl/octyl, 70/30 butyl/octyl and 60/40 butyl/octyl formulations depending on the dentist's preference. The compound, which exists in monomeric form in the plastic containers, polymerizes extremely rapidly in the presence of anions, especially of hydroxyl ions [in the presence of water]. It has the ability to adhere to moist living tissues. It demonstrates a favorable tissue response and reveals no toxic or foreign body reaction in humans.
Intended Use	PeriAcryl® is indicated to be used as an adjunct to temporarily assist in securing periodontal dressings.
Cautions:	**CAUTION:** Federal law (U.S.A.) restricts this device to sale by or on the order of a dentist.
Substantial Equivalency Information	The Family of PeriAcryl® has the same intended use and the same technological characteristics as the predicate devices listed. The chemical formulation for the Family of PeriAcryl® does not contain any new ingredients which raises additional safety and effectiveness concerns. The identified differences were determined to be minor and did not raise any concerns regarding the overall safety and effectiveness of the device.

OCT 10 2007

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Don Blacklock
President
GluStitch, Incorporated
7188 Progress Way, 307#
Delta, British Columbia
CANADA V4G 1M6

OCT 10 2007

Re: K071484
Trade/Device Name: PeriAcryl® 90, PeriAcryl® 80, PeriAcryl® 70, and PeriAcryl® 60
Regulation Number: 21 CFR 872.3275
Regulation Name: Dental Cement
Regulatory Class: II
Product Code: EMA
Dated: September 17, 2007
Received: September 26, 2007

Dear Mr. Blacklock:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

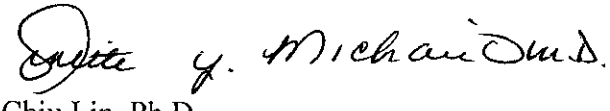
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K071484

Device Name: PeriAcryl® 90, PeriAcryl® 80, PeriAcryl® 70, and PeriAcryl® 60

Indications for Use:

PeriAcryl® 90, PeriAcryl® 80, PeriAcryl® 70, and PeriAcryl® 60 are indicated to be used as an adjunct to temporarily assist in securing periodontal dressings.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(21 CFR Part 801 Subpart D) (21 CFR Part 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K071484